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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,478	01/28/2005	Jan Sternby	02508.0106	4522
22852	7590	04/30/2009	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1797	
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			04/30/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/500,478

Applicant(s)

STERNBY ET AL.

Examiner

JOHN KIM

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3/31/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 16-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-15 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/003)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

1. Claims 1-11 and 16-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was treated as an election **without** traverse in the reply filed on 10/29/07 as indicated in previous office action.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popovich et al (US Patent No. 4,191,182) in view of Heilmann (US Patent No. 4,906,375).

Regarding claims 12 and 27, Popovich et al teach a plasmapheresis method and device comprising a blood circuit (1, 13), a fluid circuit (23) and a filter (9) having a semipermeable membrane (11) separating a fluid compartment (9b) from a blood compartment (9a) provided with means (e.g. a junction of circuits 1, 33) for mixing blood and a cleaning fluid (e.g. replacement fluid) and directing the mixture through the blood compartment (9a) and means (29 e.g. ultrafiltrate pump) for applying a pressure gradient across the membrane (11) to create an ultrafiltration into the fluid compartment (9b) (see figure 1; col. 3, line 16 – col. 4, line 35; col. 4, line 62 – col. 10, line 46). Popovich et al further teach that the replacement fluid rate (e.g. cleaning fluid) can be from 75 ml/min to 600 ml/min since recycle flow rate is maintained in the range from about 5 ml/minute/layer to about 40 ml/min/layer in 15 separate ultrafiltering membrane layers while blood flow rate is from about 20 to about 400 ml/min (see col. 9, lines 2-54). Above meets the limitation of a ratio between the cleaning fluid flow rate and a blood flow

rate at at least 5. Claims 12 and 27 essentially differ from the method and apparatus of Popovich et al in reciting a water permeability coefficient of the filter being at least 10 ml/min/mmHg and the cleaning fluid flow rate being at least 1000 ml/min. Heilmann teaches hemofiltration membranes having water permeability of about 600 ml/hr/mmHg for 1.25 m<sup>2</sup> which is converted to be 12.5 ml/min/mmHg (see col. 9, line 57 – col. 10, line 8; col. 11, lines 26-53). It would have been obvious to a person of ordinary skill in the art to substitute the hemofiltration membrane of Heilmann for the plasma filtering membrane of Popovich et al for plasmapheresis in high volume of blood. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the flow rate of cleaning fluid, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

4. Claims 13 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popovich et al in view of Heilmann as applied to claims 12 and 27 above, and further in view of Breslau (US Patent No. 4,435,289). Regarding claims 13 and 28, Popovich et al do not suggest several filters arranged in series or parallel or a combination thereof. Breslau teaches that ultrafiltration process by series flow configuration result in increased cost efficiency and reduced energy requirement by utilizing increased operating pressures and backpressurization of permeate (see abstract; figures 2-5). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to replace plasma filter with several filters arranged in series for increased cost efficiency and reduced energy requirement as suggested by Breslau (see abstract).

5. Claims 14-15 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popovich et al in view of Heilmann as applied to claims 12 and 27 above, and further in view of Brugger et al (US Patent No. 6,572,641 B2). Regarding claims 14-15 and 29-30, Popovich et al do not suggest a heater for heating blood before it is returned to the patient. Brugger et al teach a blood warming device in connection to a device (60) including ultrafiltration device (e.g. plasmapheresis) to heat blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber (see figure 3; col. 3, lines 20-29; col. 4, line 51 - col. 5, line 2). It would have been obvious to a person of ordinary skill in the art to combine the plasmapheresis device with blood warming device of Brugger et al along a path including returning blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber as suggested by Brugger et al (see col. 3, lines 20-29).
6. Claims 14-15 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popovich et al in view of Heilmann and Breslau as applied to claims 13 and 28 above, and further in view of Brugger et al (US Patent No. 6,572,641 B2). Regarding claims 14-15 and 29-30, Popovich et al do not suggest a heater for heating blood before it is returned to the patient, but Breslau teaches several filters in series as described in above paragraph 3. Brugger et al teach a blood warming device in connection to a device (60) including ultrafiltration device (e.g. plasmapheresis) to heat blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber (see figure 3; col. 3, lines 20-29; col. 4, line 51 - col. 5, line 2). It would have been obvious to a person of ordinary skill in the art to combine the plasmapheresis device with blood warming device of Brugger et al along a path in a final filter

including returning blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber as suggested by Brugger et al (see col. 3, lines 20-29).

7. Applicant's arguments with respect to claims 12-15 and 27-30 have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN KIM whose telephone number is (571)272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John Kim/  
Primary Examiner, Art Unit 1797